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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 08/460,715 | 06/02/95 | MACH | M 5552.0738-02 |

HM22/0622
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EXAMINER

WORTMAN, D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1643

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DATE MAILED:

06/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/460,715

Applicant(s)
Mach et al.

Examiner
Donna C. Wortman, Ph.D.

Group Art Unit
1643



☒ Responsive to communication(s) filed on 11/30/98 and 3/5/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 7, 8, and 19-24 is/are pending in the application.

Of the above, claim(s) 7 and 8 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 19-24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 7, 8, and 19-24 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Claims 5, 17, and 18 were cancelled and new claims 19-24 were added in Paper No. 13 filed 11/30/98. Claims 7 and 8 have been withdrawn from consideration as drawn to an invention previously non-elected with traverse. Claims 19-24 are under examination at this time.

The disclosure is objected to because of the following informalities:

The disclosure does not contain a BRIEF DESCRIPTION OF THE DRAWING.

Appropriate correction is required.

The receipt of a certified translation of the priority document is acknowledged.

The rejection as previously offered under 35 USC 102(a) is withdrawn in view of the receipt of the above-mentioned certified translation.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 21, 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated and purified DNA sequence that encodes HCMV pp28 from human cytomegalovirus strain AD169 as disclosed in the instant specification and represented in Fig. 1, and the DNA that encodes a fusion protein comprising HCMV pp28 from human cytomegalovirus strain AD169, does not reasonably provide enablement for the DNA encoding any and all

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immunogenic parts thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. The specification does not provide any guidance as to which portions or epitopes of HCMV pp28 cause the production of antibodies during HCMV infection; taking into account the state of the art at the time the invention was made, the amount of guidance presented in the specification, and the lack of predictability inherent in the field, one of skill in the art would be unable to practice the invention with respect to the immunogenic portions of pp28 without an undue amount of experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19-21 are indefinite in reciting "A DNA structure" since it is not clear what a DNA "structure" is intended to mean. Is it different from a DNA molecule?

Claim 19 is indefinite in reciting "immunogenic parts thereof" since it is not clear what this encompasses. Are the parts immunogenic in the sense that antibodies are produced to certain viral epitopes in humans in the course of natural infections? Are they immunogenic in the

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broader sense that nearly any peptide that can be encoded by a portion of the DNA encoding HCMV pp28 can be rendered immunogenic so as to raise antibodies in animals? The intended limitations of "immunogenic parts" are not clear.

Claim 19 is indefinite in reciting "said DNA" without clear antecedent in the preceding part of the claim which recites "A DNA structure."

Claim 19 is indefinite in reciting "does not comprise the 6.5 kB HindIII R fragment from the genome of human cytomegalovirus strain AD169" since the metes and bounds of the claim are not clear. Is it intended that the claim encompass the corresponding HindIII R fragment in all strains except the AD169 strain? Does it encompass the entire HCMV genome; or fragments that comprise the portion of the genome that encode HCMV pp28, or fragments larger than the HindIII R fragment in any and all HCMV strains? Clarification is needed.

Claim 21 is indefinite in reciting "said construct" without antecedent.

Claims 22, 23, and 24 are indefinite in reciting "the DNA structures" of claims 19, 20, and 21, respectively, since claims 19, 20 and 21 recite "structure" in the singular.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19, 21, 22 and 24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ihara et al. (Archives of Virology 88:241-250, 1986, cited on PTO 892, attached). Ihara discloses a cosmid clone and bacteria containing the HindIII DNA structure of human cytomegalovirus Towne strain that inherently contains the DNA encoding the phosphoprotein which is either the same as, or an obvious variant of, the HCMV pp28 of strain AD169.

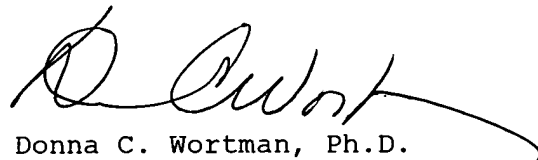
Because this rejection contains new grounds of rejection beyond those required by Applicant's most recent amendment, it is made non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman

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whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Eisenschenk can be reached at (703) 308-0452. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Donna Wortman, Art Unit 1643 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1643 FAX telephone number is (703) 305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday, or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.



Donna C. Wortman, Ph.D.
Primary Examiner

June 21, 1999